UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,762	10/24/2003	Toni A. Armstrong	MONS:127USC1	8955

73905 7590 08/27/2009

SONNENSCHEIN NATH & ROSENTHAL LLP
P.O. BOX 061080
SOUTH WACKER DRIVE STATION, WILLIS TOWER
CHICAGO, IL 60606

EXAMINER	
HWU, JUNE	

ART UNIT	PAPER NUMBER
1661	

MAIL DATE	DELIVERY MODE
08/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,762	ARMSTRONG ET AL.	
	Examiner	Art Unit	
	JUNE HWU	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,20-22,27,31-33,35,37-41,43,45,49-52 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,20-22,27,31-33,35,37-41,43,45,49-52 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 2, 2009 has been entered.

Status of the Claims

Claims 2-19, 23-26, 28-30, 34, 36, 42, 44, 46-48, 53 and 55-58 are cancelled and claims 1, 20-22, 27, 31-33, 35, 37-41, 43, 45, 49-52 and 54 will be examined on the merits.

The rejection over claims 8 and 10-12 under 35 U.S.C. 103(a) as being unpatentable over Firoozabady et al (In Vitro Cell. Dev. Biol. 299:166-178, 1993) in view of Davis et al (*In Vitro* vol. 9, no. 6, 1974, pp. 395-398) is withdrawn due to Applicants' amendment to the claims.

The rejection over claim 13 under 35 U.S.C. 103(a) as being unpatentable over Firoozabady 1993 in view of Davis et al as applied to claim 8 and 10-12 above, and further in view of Rangan 1998 is withdrawn due to Applicants' amendment to the claims.

The rejection over claims 14, 17 and18 under 35 U.S.C. 103(a) as being unpatentable over Firoozabady 1993 in view of Chi et al (Plant Cell Reports (1990) 9: 195-198) is withdrawn due to Applicants' amendment to the claims.

The rejection over claim 19 under 35 U.S.C. 103(a) as being unpatentable over Firoozabady 1993 in view of Chi et al as applied to claims 14, 17 and 18 above, and further in view of Rangan 1998 is withdrawn due to Applicants' amendment to the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Finer (Canadian Patent 1,309,367) in view of Rangan et al (U.S. Patent No. 5,834,292, 1998).

Finer teaches a method of producing pro-embryonic cotton cell masses that are capable of regenerating into mature embryos, plantlets and whole plants (abstract and p. 3, lines 26-28). The explant used for the induction of cotton callus was hypocotyl (p. 4, last par. and p. 5, 2nd par.). The callus formed may be unorganized or may contain pro-embryonic cell masses, embryogenic callus and/or embryos (p. 7, 5th par.). The callus may be induced in the dark (p. 8, 1st par.). The development of the callus is placed in a liquid medium to promote development of pro-embryonic or proliferating embryonic cell masses (p. 8, 2nd par.) and may be cultured under dark lighting condition (p. 9, 2nd par.). The pro-embryonic cell masses are transferred to a liquid medium with auxin and may be cultured under dark condition (p. 10, 4th par.). The pro-embryonic cell masses are placed in a medium that induces the development of the mature embryo (p. 11). These embryos may be cultured under dark condition (p. 12, 3rd par.). The embryos are maintained in developing medium until the embryos have matured into torpedo or mature states (p. 12, 4th par.). The matured embryos are placed in a solid medium for germination and once germinated the plantlets are transferred to soil for further growth into plants (p. 14, 1st par.). Example 2 teaches that hypocotyls were excised and sliced then placed on Medium #2 (p. 16). When the callus tissue proliferated it was placed in Medium #3. In Example 3, the callus tissue was placed in Medium #4, wherein the tissue proliferated (p. 16).

Example 4 shows that the embryos formed when placed on Medium #5 and then shoots and roots developed and finally plantlets were formed (p. 16).

Finer does not teach the transformation of callus tissue.

Rangan 1998 teach a method of transforming cotton callus, wherein the callus is placed in a medium containing *Agrobacterium* for 1 minute to 24 hours. The callus was removed and incubated in callus growth medium. After incubation, the developing callus was transferred to MS medium supplemented with NAA, cefotaxime and kanamycin. The transformed callus was selected (Examples 20-23). The results of the transformation of the cotton species to plants are shown in Example 26. Rangan 1998 further taught that the mature somatic embryos are capable of germinating and regenerating into whole plants according to his method of producing cotton plants (col. 11, lines 23-27). Cotyledons and/or hypocotyls segments may be used (col. 10, lines 22-24). Fig. 10 shows transformed calli developing into somatic embryos (col. 11, lines 31-33). Fig. 11 shows transformed somatic embryos (col. 11, lines 33-36). Fig. 12 shows plants formed from the embryos of Fig. 11 (col. 11, lines 36-37). Thus, the cotton callus tissue is regenerable.

Although the references are silent to distinguishing between non-embryogenic and embryogenic callus tissue, it is known in the art that non-embryogenic callus are composed of undifferentiated cells that have not undergone embryogenesis and embryogenic callus are capable of differentiating when placed in the proper medium for further development. Finer taught that the callus cells starts off as non-embryogenic by stating that "Normally, when hypocotyls or cotyledons are used as explant source, the callus appears to be unorganized" (p. 7). The callus from Finer step (a) is suspended in a liquid medium to promote pro-embryogenic or proliferating embryogenic cell mass (p. 8). Moreover, Rangan 1998 taught that cotton explant is cultured in callus growth medium until undifferentiated callus is formed then culturing

the undifferentiated callus in callus growth medium until embryogenic callus is formed and then finally the development of plantlets (abstract and col. 8, lines 15-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of inducing the formation of regenerable embryogenic cotton callus tissue from hypocotyl under dark lighting condition as taught by Finer and to combine that method by transforming the non-embryogenic cotton callus tissue in medium and obtaining regenerable embryogenic callus as taught by Rangan 1998. One of ordinary skill in the art would have been motivated to do so given that cotton is an important fiber crop. Moreover, Finer taught that method steps (a)-(c) may be used to produce cells or plants with desirable characteristics, such as herbicide tolerance (p. 14). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of transforming non-regenerable embryogenic cotton callus under dark lighting condition as taught by Finer and Rangan 1998 because dark lighting condition would be a choice of experimental design and is considered within the purview of the cited prior art. Moreover, culturing callus tissue under dark lighting condition would prevent the greening of the callus tissue.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

Response to Arguments

Applicants' arguments filed July 2, 2009 have been fully considered but they are not persuasive.

Applicants argue that Finer teaches in Example 2 at page 16 that callus was induced from seedling hypocotyls and that Example 2 does not state that the callus is embryogenic (response p. 8).

This argument is not found persuasive because the instant specification defines "embryogenic callus" as a type of callus capable of differentiating into somatic embryos (p. 9 of instant specification). Finer taught in Example 4 that embryos were formed in Medium #4, thus the callus tissue in Example 3 must have been embryogenic because it formed into embryos.

Applicants argue that Finer does not teach conversion of cotton callus tissue, derived hypocotyl tissue, from a non-embryogenic state to an embryogenic state (response p. 8).

This argument is not found persuasive because Finer taught that the hypocotyls are the preferred explants for embryogenic cotton callus (p. 4, last par.). The tissue starts out as non-embryogenic callus until it is placed in the induction medium, wherein the formation of callus may be unorganized or may contain pro-embryonic cell masses, embryogenic callus and/or embryos (p. 7). The resulting callus is then transferred to a callus subculture medium similar to the callus induction medium for a period of time for further development (p. 7, last par.). The callus tissues from step (a) are transferred to a liquid medium to promote development of pro-embryonic or proliferating embryonic cell masses (p. 8). Thus, the cells are "embryogenic callus". The embryos formed shoots and roots and the germinating embryos are placed in pots for development into plantlets (p. 12 and p. 16). Finer further taught obtaining non-embryogenic cotton callus tissue derived from hypocotyls (p. 7 and Example 2). Moreover, the rejection is based on a combination of references Finer in view of Rangan 1998 where Finer taught a method of regenerating cotton tissue under dark light condition and Rangan 1998 taught a method of transforming cotton callus tissue.

Applicants argue that Finer does not teach in Example 3 that the callus tissue is not derived from hypocotyls because Finer teaches at page 7 that the embryogenic callus formed was derived from somatic embryos and not from hypocotyls explants (response p. 9).

This argument is not found persuasive because Example 2 describes that hypocotyls are excised. Then in Example 3 the next step would have been the use of the hypocotyls tissues from Example 2 to allow the callus to proliferate. The next step would be to develop embryos from Example 3 to further proliferate in Medium #5 and then transferring the developed embryos to Medium #6. Finer does not state in Examples 1-4 that cotyledons or somatic embryos were used. Moreover, p. 4 states that "cotyledons or hypocotyls are preferred" and claim 6 states, "The method of claim 1, 2, 3 or 4 wherein the cotton plant tissue in step (a) is cotyledon or hypocotyls tissue." With regard to page 7 that the embryogenic callus formed derived from somatic embryos is not found persuasive because as stated above Examples 2-4 appear to show that the callus tissue was derived from hypocotyls. Moreover, claim 6 states that the cotton plant tissue in step (a) is hypocotyl tissue.

Applicants argue that the MPEP 2143.03 states that all claim limitation must be considered and instant claim 1 is not rendered obvious by Examples 2-4 in Finer (response p. 9).

This argument is not found persuasive because all of the limitations in instant claim 1 have been considered. As stated above, Finer taught that the callus tissue in Example 2 was from hypocotyls. Moreover, in claim 6, the claim states that the cotton plant tissue is hypocotyl tissue.

Applicants argue that the recitation from Finer "teaches that hypocotyls are the preferred explants for embryogenesis cotton callus" was a mistake (response p. 9).

This argument is not found persuasive because as stated above Examples 2-4 and claim 6 taught that the cotton callus was derived from hypocotyls.

Applicants argue that the experiments of Finer Examples 2-4 were all performed with a 16:8 light/dark photoperiod and that all claim limitation must be considered (MPEP 2143.03) (response p. 9).

This argument is not found persuasive because Finer also taught that the callus tissue may be induced in the dark. Thus, the claim limitation with regard to dark condition has been considered.

Applicants reiterate that all claim limitation must be considered and claim 1 is not rendered obvious by Finer (response p. 9).

This argument is not found persuasive because Applicants are attacking the references individually. One cannot show nonobviousness by attacking references individually wherein the rejection is based on a combination of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Rangan 1998 was combined with Finer to show that it would have been obvious to use the method of cotton transformation as taught by Rangan 1998 with the method of inducing the formation of regenerable embryogenic cotton callus as taught by Finer.

Applicants argue that the instant application demonstrates significant and unexpected improvements in tissue culture efficiency from the use of dark culture conditions and that Finer nor Rangan demonstrate production of embryogenic callus under dark conditions (response pp. 9-10).

This argument is not found persuasive because Finer taught that the callus may be induced in the dark or light (p. 8). MPEP 716.01(c) states “The arguments of counsel cannot take place of evidence in the record *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718

(CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant." Applicants have not shown any factual evidence that support unexpected results. The MPEP 716.02(a) states, “Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage.” With regard to Rangan 1998, Rangan 1998 was combined with Finer to show the transformation of the cotton callus tissue. With regard to the instant application demonstrating significant and unexpected improvements under dark culture conditions, it is noted that the instant specification in Table 2 in Experiment 2 shows greater than significant results of embryogenesis when compared to light and black bags; however, Experiments 1 and 3-4 do not show greater than significant results on the induction of embryogenesis under dark conditions.

Applicants argue that Finer does not provide any teachings regarding growth of different type of callus (e.g. non-embryogenic or embryogenic) in different light conditions (e.g. dark, or 16:8 light: dark photoperiod) (response p. 10).

This argument is not found persuasive because Example 2 appears to demonstrate embryogenic callus tissue because when the callus was transferred to Medium 2, the callus tissue proliferated. Thus, the callus tissue was embryogenic because the callus tissue eventually proliferated into embryos (Example 4). With regard to the light conditions Finer taught that callus may be induced in dark (p. 8).

Applicants argue that Finer does not teach or suggest that dark conditions are beneficial during the growth on embryogenesis-inducing medium in order to yield embryogenic callus (response p. 10).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that dark conditions are beneficial during the growth on embryogenesis) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue that Finer does not recognize or teach that dark conditions are a result-effective variable amenable to optimization as to the timing of a dark culture step and cites MPEP 2144.05 (II) (B) (response pp. 10-11).

This argument in not found persuasive because as stated above Finer taught that callus may be induced in the dark. The MPEP 2121 states, "When the references relied on expressly anticipates or makes obviousness all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on the applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207, USPQ 107 (CCPA) 1980. See also § 716.07." With regard to MPEP 2144.05 (II) (B), Finer taught that dark may be used to culture the callus tissue. Even though, Finer does not teach through example, the use of dark lighting conditions was suggested for the induction of cotton callus.

Applicants reiterate that Finer's teachings do not distinguish between non-embryogenic or embryogenic growth (response p. 11).

This argument is not found persuasive because as stated above Finer taught in step (a) non-embryogenic callus cells and step (b) that callus cells from step (a) is transferred to liquid

medium which promotes the development of pro-embryonic or proliferating embryonic cell mass.

Applicants argue that 11 years passed between the priority dates of Finer and of the present Application and that the use of dark culture conditions was not an obvious parameter for a skilled artisan in order to improve embryogenesis (response p. 11).

In response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Applicants argue that Rangan 1998 teaches that the callus cells were cultured under 16:8 hour light/dark regime (response p. 11).

This argument is not found persuasive because Applicants are attacking the references individually. Rangan 1998 was combined with Finer to show that it would have been obvious to use the method of cotton transformation as taught by Rangan 1998 with the method of inducing the formation of regenerable embryogenic cotton callus as taught by Finer.

Applicants are unclear why Rangan 1998 was combined with Finer regarding transformation, yet Rangan 1998 teaches the use of 16 hour photoperiod and that this is a *prima facie* demonstration of hindsight reasoning (response p. 12).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392,

170 USPQ 209 (CCPA 1971). As stated above, Finer taught a method of regenerating cotton callus, wherein the callus cells may be cultured in the dark and combined with Rangan 1998 who taught transformation of cotton callus.

Applicants reiterate that the present application demonstrates unexpected results regarding embryogenesis under dark conditions and cite examples from the instant specification (response p. 12).

This argument is not found persuasive because as stated above Applicants have not shown any evidence that the prior art results were greater than expected when compared to the instant application. The examples in the claimed invention are conclusion of unexpected result but do not support any factual evidence to support the allegation.

Applicants argue that Finer in view of Rangan 1998 do not teach or suggest the use of dark culture conditions (response p. 12).

This argument is not found persuasive because Finer taught that the cotton callus tissue derived from the hypocotyl may be culture in the dark and Rangan 1998 taught transformation of cotton callus derived from hypocotyls (Examples 20-23). Thus, it would have been obvious to one of ordinary skill in the art to combine the teachings of Finer in view of Rangan 1998.

Applicants argue that Rangan 1998 represents a new rejection because Rangan 1998 teaches embryogenesis (response p. 13).

This argument is not found persuasive because the Final Rejection filed on March 2, 2009 at page 5 was responding to the arguments that Finer did not teach conversion of cotton callus tissue derived from hypocotyls tissue, from a non-embryogenic state to embryogenic state. Rangan 1998 was mentioned to further show that embryogenic callus was formed from undifferentiated callus.

Applicants argue that Rangan 1998 is mischaracterized because Example 26 does not show that transformed plants were obtained, but rather that tissue from plants were transformed (response p. 13).

This argument is not found persuasive because Example 26 does show the results of regenerable embryogenic callus tissues that transformed into plants. In the table of Example 26, the column under "C^1" describes the varieties such as, Acala SJ2, Acala SJ5, Acala SJ-C1, Acala CG510, Acala B1644, Acala B1654-26, Acala B1654-43, Acala B1810, Acala B2724, Acala B4894, Coker 315, Stoneville 506, Chembred B2, Chembred C4 and Siokra that were transformed in the callus stage. Under column P^3 all of the varieties listed above transformed into plants. Moreover, Example 21 showed that the method of Example 20 was used to transform plants, embryos and callus (col. 26, lines 45-51). Thus, Example 26 does show the transformation of cotton callus to transformed plants. In addition, col. 7, lines 28-58 taught that mature plants were obtained from callus culture derived from hypocotyls. Therefore, Example 26 shows the results of transformed regenerable embryogenic callus tissues.

Applicants argue that Example 18 and 26 teach the use of a 16 hour photoperiod, unlike the instant invention in Example 1 with dark lighting conditions and cites MPEP 2143.03 (response p. 13).

This argument is not found persuasive because as discussed above the rejection is based on a combination of references Finer in view of Rangan 1998. With regard to MPEP 2143.03 all of the limitations in claim 1 have been considered in this rejection.

Claims 20-22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finer in view of Rangan 1998, further in view of Davis et al (*In Vitro* vol. 9, no. 6, 1974, pp. 395-398) and further in view of Chi et al (Plant Cell Reports (1990) 9: 195-198).

The teachings of Finer in view of Rangan 1998 are discussed above.

Finer in view of Rangan 1998 do not teach that the medium is supplemented with AVG and ascorbic acid.

Davis et al teach a method of culturing cotton (*Gossypium hirsutum*) callus derived from leaf explant (p. 395, left col., 2nd paragraph) in medium containing 5 mg/l of ascorbic acid (p. 395, right col., lines 9-10), which is between about 1 mg/L and 1000 mg mg/L. The cotton callus formed within 36 days when 5 mg of ascorbic acid was added to the LS medium (p. 396, right col. 1st full paragraph). Removal of healthy callus tissue was followed by regeneration of vigorous non-pigmented callus tissue which grew well when transferred to fresh medium containing myoinositol and ascorbic acid (p. 397, left col., lines 2-7).

Chi et al teach that AVG enhanced shoot regeneration from cotyledons of *Brassica*, a dicot. Cotyledons and hypocotyls of *Brassica* were excised and cultured on medium containing 20 µM AVG (p. 195 right col. last paragraph to p. 196, left col., line 4 and Table 1), which is between about 1 mM and 100 mM. Chi et al noted that there had been evidence that ethylene effected growth and differentiation of plant cells and tissues and that ethylene inhibition enhanced plant regeneration of *Nicotiana* and *Triticum*, increased protoplast growth of *Solanum*, promoted embryo production in anther cultures of *Brassica* and somatic embryogenesis of *Daucus* (p. 195, left col.).

Although Chi was silent to the use of AVG in cotton plants, one of ordinary skill in the art would have been motivated to use AVG in cotton because Chi noted that there had been evidence that AVG effected growth and differentiation of plant cells (p. 195, left col.). Thus, it would have been obvious to one of ordinary skill to use AVG on cotton explants.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of culturing transformed regenerable non-embryogenic cotton callus

tissue under dark lighting condition as taught by Finer in view of Rangan 1998 and to combine that method by adding ascorbic acid as taught by Davis and also adding AVG as taught by Chi. One of ordinary skill in the art would have been motivated to do so given that the addition of ascorbic acid reduced the formation of black pigments in callus and that AVG has shown that without ethylene inhibitor the explants were poorly regenerative (p. 197, right col. 3rd full par.). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of methods as taught by Finer in view of Rangan 1998 and further in view of Davis and Chi because the addition of ascorbic acid and ethylene inhibitor would be a choice of experimental design and is considered within the purview of the cited prior art. Moreover, it is noted by Chi that the addition of AVG aided plant regeneration and ascorbic acid prevented browning of the callus tissue as taught by Davis.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in inducing the formation of regenerable embryogenic cotton callus as claimed. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

Response to Arguments

Applicants argue that Finer provides only mention the use of dark conditions and does not actually use them in any working examples (response p. 14).

This argument is not found persuasive because Finer does state that dark condition may be used in culturing cotton callus. Furthermore it is the Applicants burden to provide evidence that the dark condition is inoperable (see MPEP 716.07). Moreover the rejection is based on a combination of references Finer in view of Rangan 1998 further in view of Davis and further in view of Chi.

Applicants argue that Finer does not recognized that timing of use of dark culture conditions is a result-effective variable that might be of interest for optimization (MPEP 2144.05 (II) (B)) and that the present invention demonstrates unexpected improvement in embryogenesis when dark condition is used (instant Examples 2, 3, and 9) (response pp. 14-15).

This argument is not found persuasive because as stated above Finer taught that callus tissue may be induced in the dark (p. 8). With regard to the unexpected improvement instant Examples 2, 3, and 9, Applicants have not provided factual evidence to support unexpected results. As stated above, Applicants have not shown results that were greater than those that would have been expected from the prior art. Moreover, as stated above the examples in the claimed invention are conclusion of unexpected result but do not support any factual evidence to support the allegation of unexpected results when culturing cotton callus tissue under dark lighting condition and obtaining regenerable embryogenic callus tissue.

Claims 31-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finer in view of Rangan 1998, further in view of Davis, further in view of Chi as applied to claims 20-22 and 27 above, and further in view of Klimaszewska et al (U.S. Patent No. 6,200,809 B1).

The teachings of Finer in view of Rangan 1998, further in view of Davis, and further in view of Chi are discussed above.

Finer in view of Rangan 1998, further in view of Davis, and further in view of Chi do not teach that the support matrix is filter paper.

Klimaszewska et al teach that embryogenic tissue from any plant species, including angiosperms (col. 11, lines 28-36 and claim 2) is placed on a porous support matrix, such as

filter paper for embryo maturation (col. 9, lines 25-30). The embryonal mass on the filter paper was placed on the maturation medium (Example 1 and Fig. 1a).

Although Klimaszewska is silent with the culturing of transgenic embryogenic cotton tissue, one of ordinary skill in the art would have been motivated to do so given that the embryos produced by his method are of superior quality and show greater germination rates when compared with other maturation methods (col. 11, lines 13-16). In addition, the medium could be refreshed without removing the culture from the support (col. 11, lines 16-18).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the teachings of culturing transgenic cotton embryos in medium containing antioxidant and ethylene inhibitor under dark lighting condition to produce transgenic embryogenic callus tissue as taught by Finer in view of Rangan 1998, further in view of Davis, and further in view of Chi et al and to modify that method by using filter paper as the support matrix as taught by Klimaszewska because support matrix resulted in higher quality and greater germinating success of embryos (col. 11, lines 13-16). Moreover, one of ordinary skill in the art at the time the invention was made would use the method of culturing transgenic cotton callus tissue grown under dark lighting conditions and the addition of ascorbic acid and AVG as taught by Finer, in view of Rangan 1998, further in view of Davis, and further in view of Chi and to combine that method by using filter paper as the porous support matrix because the success of embryo maturation with a porous support matrix as taught by Klimaszewska (col. 11, lines 13-16).

Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Finer in view of Rangan 1998, further in view of Davis, further in view of Chi, and further in view of Klimaszewska, because these methods would be a choice of

experimental design and is considered within the purview of the cited prior art to produce regenerable callus tissue.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

Response to Arguments

Applicants reiterate that Finer provides only the most cursory mention of the use of dark conditions and does not actually use them in any working examples (response p. 15).

This argument is not found persuasive because as stated above Finer does state that dark condition may be used in culturing cotton callus. Furthermore it is the Applicants burden to provide factual evidence that the dark condition is inoperable (see MPEP 716.07). Moreover the rejection is based on a combination of references Finer in view of Rangan 1998, further in view of Davis, further in view of Chi, and further in view of Klimaszewska.

Applicants argue that Finer does not recognized that timing of use of dark culture conditions is a result-effective variable that might be of interest for optimization (MPEP 2144.05 (II) (B)) and that the present invention demonstrates unexpected improvement in embryogenesis when dark condition is used (instant Examples 2, 3, 6 and 9) (response pp. 15-16).

This argument is not found persuasive because as stated above Finer taught that callus tissue may be induced in the dark (p. 8). The examples in the claimed invention are conclusion of unexpected result but do not support any factual evidence to the allegation of unexpected improvement in embryogenesis under dark condition. As stated above, Applicants have not shown results that were greater than those that would have been expected from the prior art.

Claims 37-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finer in view of Davis et al, further in view of Chi et al, further in view of Klimaszewska, and further in view of Rangan 1993 (U.S. Patent No. 5,244,802, 1993).

The teachings of Finer are discussed above.

Finer does not teach that the cotton callus tissue medium contains antioxidant, ethylene inhibitor, amino acid hydrolysate and support matrix.

The teachings of Davis are discussed above, with regard to supplementing the culture medium with an antioxidant (ascorbic acid).

The teachings of Chi are discussed above, with regard to supplementing the culture medium with ethylene inhibitor (AVG).

The teachings of Klimaszewska are discussed above, with regard to the culture medium containing a support matrix (filter paper).

Rangan 1993 teaches a method of cotton regeneration, wherein the cotton cotyledons were cut into segments (col. 12, lines 5-6) and cultured in media until callus formed then the callus was transferred to suspension medium for further regeneration (col. 13, lines 5-7). After three to four subcultures on Beasley & Ting medium containing 500 mg/l casein hydrolysate (amino acid hydrolysate), the embryogenic callus produced embryos (col. 13, lines 66-68). These embryos eventually developed into plants (col. 14, lines 1-3). The seedling explants can also be transformed (col. 10, line 36 and examples 9-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of culturing regenerable non-embryogenic cotton callus tissue under dark lighting conditions as taught by Finer and to combine that method by culturing the callus tissue with ascorbic acid as taught by Davis, AVG as taught by Chi, casein hydrolysate as

taught by Rangan 1993 and filter paper as taught by Klimaszewska because these methods would improve the development of the callus tissue. One of ordinary skill in the art would have been motivated to do so given that ascorbic acid would reduce the amount of browning of the callus tissue as taught by Davis; AVG would aid in the growth and differentiation of cells as taught by Chi; casein hydrolysate would aid in the growth of tissue; supporting the callus on filter paper as taught by Klimaszewska would produce higher quality embryos; and supplementing the cotton tissue medium with casein hydrolysate as taught by Rangan 1993 would aid in the development of embryos.

Although none of the cited references specifically teach that an antioxidant, an ethylene inhibitor, and filter paper material are combined to the callus medium under dark lighting condition, one of ordinary skill in the art would have been motivated to use antioxidant, ethylene inhibitor, and filter paper because antioxidant improved the growth of callus tissue; ethylene inhibitor improved the growth and differentiation of callus tissue; and filter paper would aid in further development of the embryos all under dark lighting condition for culturing regenerable embryogenic cotton callus tissue.

With regard to the concentration of amino acid, it would have been obvious to adjust the concentration to fit the needs of the explant. It is noted that Davis used about 0.2 g (200mg) of casein hydrolysate which is between about 50 mg/L and about 150 mg/L. Moreover, all of these supplements to the culture medium would improve the culturing of embryogenic cotton tissue.

Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Finer in view of Davis, further in view of Chi, further in view of Klimaszewska, and further in view of Rangan 1993 because these methods would be a choice of experimental design and is considered within the purview of the cited prior art to produce regenerable callus tissue.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

Response to Arguments

Applicants reiterate that Finer provides only the most cursory mention of the use of dark conditions and does not actually use them in any working examples (response p. 17).

This argument is not found persuasive because as stated above Finer does state that dark condition may be used in culturing cotton callus. Furthermore it is the Applicants burden to provide factual evidence that the dark condition is inoperable (see MPEP 716.07). Moreover the rejection is based on a combination of references Finer in view of Davis, further in view of Chi, further in view of Klimaszewska, and further in view of Rangan 1993.

Applicants reiterate that Finer does not recognized that timing of use of dark culture conditions is a result-effective variable that might be of interest for optimization (MPEP 2144.05 (II) (B)) (response pp. 17-18).

This argument is not found persuasive because as stated above Finer taught that callus tissue may be induced in the dark (p. 8). Applicants have not provided any support of factual evidence on unexpected improvement in embryogenesis under dark condition.

Applicants reiterate that the instant invention demonstrates unexpected improvement in embryogenesis and overall efficiency of obtaining transformed cotton plants when dark culture conditions are used in conjunction with other experimental parameters (response p. 18).

This argument is not found persuasive because as stated above Applicants have not shown any factual evidence that the prior art and the instant application show greater than expected results. Moreover, the instant claims are not limited to transformed cotton plants.

Claims 45 and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Finer in view of Rangan 1998 and further in view of Perlman (U.S. Patent No. 5,341,557).

The teachings of Finer are discussed above.

Finer does not teach the transformation of callus tissue culture is wrapped with a sealing material.

The teachings of Rangan 1998 are discussed above.

Perlman teaches that laboratory film is used to cover or seal laboratory devices such as samples of vegetables (col. 4, lines 61-65). Although Perlman is silent to wrapping with sealing material on the transgenic embryogenic cotton tissue culture, one of ordinary skill in the art would have been motivated to do so given that wrapping with sealing material would hold in moisture and prevent contamination.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of culturing regenerable transgenic embryogenic cotton tissue under dark lighting conditions as taught by Finer in view of Rangan 1998 and to combine that method with wrapping the culture with laboratory film as taught by Perlman because laboratory film is used to form a tight enclosure (col. 1, lines 10-12). One of ordinary skill in the art would have been motivated to do so given that sealing the culture would prevent evaporation, accidental opening and passage of water and chemical vapors in the closures (col. 9, lines 1-13). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Finer in view of Rangan 1998 and further in view of Perlman because applying laboratory film would be a choice of experimental design and is considered within the purview of the cited prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

Claims 50-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finer in view of Davis et al, further in view of Chi et al, further in view of Klimaszewska, further in view of Rangan 1993 as applied to claims 37-41 and 43 above, and further in view of Perlman.

The teachings of Finer in view of Davis et al, further in view of Chi et al, further in view of Klimaszewska and further in view of Rangan 1993 are discussed above.

Finer in view of Davis et al, further in view of Chi et al, further in view of Klimaszewska and further in view of Rangan 1993 do not teach that the culture is wrapped with sealing material.

The teachings of Perlman are discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to culture regenerable non-embryogenic cotton callus tissue containing ascorbic acid and AVG in medium under dark lighting conditions and culturing the embryogenic cotton tissue in medium with filter paper and casein hydrolysate under dark lighting or low light as taught by Finer in view of Davis et al, further in view of Chi et al, further in view of Klimaszewska, further in view of Rangan 1993 and to combine that method with wrapping with sealing material as taught by Perlman. One of ordinary skill in the art would have been motivated to do so given that sealing material would reduce contamination in the culture medium. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Finer in view of Davis et al, further in view of Chi et al, further in view of Klimaszewska further in

view of Rangan 1993, and further in view of Perlman because wrapping with sealing material would be a choice of experimental design and is considered within the purview of the cited prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the cited references.

Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants reiterate that Finer provides only the most cursory mention of the use of dark conditions and does not actually use them in any working examples (response p. 19).

This argument is not found persuasive because as stated above Finer does state that dark condition may be used in culturing cotton callus. Furthermore it is the Applicants burden to provide factual evidence that the dark condition is inoperable (see MPEP 716.07). Moreover the rejection is based on a combination of references Finer in view of Davis, further in view of Chi, further in view of Klimaszewska, further in view of Rangan 1993, and further in view of Perlman.

Applicants reiterate that Finer does not recognized that timing of use of dark culture conditions is a result-effective variable that might be of interest for optimization (MPEP 2144.05 (II) (B)) (response p. 19).

This argument is not found persuasive because as stated above Finer taught that callus tissue may be induced in the dark (p. 8). Applicants have not provided any support of factual evidence on unexpected improvement in embryogenesis under dark condition.

Applicants reiterate that the instant invention demonstrates unexpected improvement in embryogenesis and overall efficiency of obtaining transformed cotton plants when dark culture conditions are used in conjunction with other experimental parameters (response p. 19).

This argument is not found persuasive because as stated above Applicants have not shown any factual evidence that the prior art and the instant application show greater than expected results. Moreover, the instant claims are not limited to transformed cotton plants.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/June Hwu/
Primary Examiner, Art Unit 1661